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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,870	11/05/2003	Fritz Sieber	650053.91649	6714

7590 04/28/2006

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/701,870	SIEBER ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-12,26-30 and 52-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *26-30 and 57* is/are allowed.

6)☒ Claim(s) *2,4-6,8,9 and 52-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office action is in response to Applicants' remarks received February 6, 2006. Claims 1, 3, 13-25, and 31-51 are canceled. Claims 2, 4-12, 26-30, and 52-66 are pending and currently under examination.

Priority: The priority date is November 6, 2002.

Withdrawal of Objections and Rejections

The rejection of claims 2, 4-6 and 8-9 under 35 U.S.C. 102(b) as being anticipated by Labrenz et al. (2000 Science 290(5497): 1744-1747) is withdrawn.

Maintenance of Objections and Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4-6 and 8-9 are rejected again under 35 U.S.C. 102(b) as being anticipated by Lou et al. (1993 Clinical Chemistry 39(4): 619-624). Lou et al. teach a rapid, one-step competitive immunochromatographic assay to measure lipoprotein(a) (Lp(a)) in plasma. To prepare one component of the assay strip, Lou et al. teach 1 mL of colloidal selenium solution was adjusted to pH 8.0 by adding 50 uL borate buffer, followed by the addition of 10 ug of Lp(a) protein (p. 620, col. 2; claims 2, 4-6, 8-9). The colloidal mixture was gently vortex-mixed for 2 min. and added to 10 uL of 100 g/L

polyethylene glycol to block and stabilize the Lp(a)-coated colloidal selenium (620; claims 2, 4-6, 8-9).

In their remarks, Applicants assert the colloid selenium prepared by Lou et al. is provided in Devereaux et al. (submitted by Applicants), which discloses the colloid selenium was precipitated and washed by centrifugation. According to Applicants, a skilled artisan would appreciate that any particles that can be pelleted by such modest g-force will be at least 2 order of magnitude larger than the size of the Se(0) particles recited in the instant claims. Furthermore, Applicants assert anticipation requires the disclosure in a single prior art reference each element of the claim under consideration and that the instant claims specifically recite (directly or indirectly) Se(0) particles with diameters of 0.4 to 5 nm and 0.4 to 1 nm. Examiner acknowledges Applicants' remarks and will address the arguments now. However, as explained in the November 4, 2005 Office action, while Applicants have provided support for the Se(0) particles having a diameter of 0.4 to 50 nm, 0.4 to 5 nm, or 0.4 to 1 nm (p. 8, [00042]), they have not provided support that the Se(0) particles in the instant invention or in their possession have the specified diameters. None of the working examples in the specification disclose an actual measurement of the diameters of the Se(0) particles of the instant invention. Zhang et al. (2001 BioFactors 15: 27-38; IDS and previously cited) teach transmission electron microscopy (TEM) was used to measure their Se(0) particles (p. 28). Therefore, since Applicants have not provided evidence that the Se(0) particles of

the instant invention have diameters of 0.4 to 5 nm and 0.4 to 1 nm, the instant claims can be anticipated by a composition comprising elemental Se and/or a colloid Se.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al. (1993 Clinical Chemistry 39(4): 619-624) in view of Zhang et al. (2001 BioFactors 15: 27-38; IDS). The teachings of Lou et al. are outlined above. The colloid selenium prepared by Lou et al. is provided in Devereaux et al. (EP 0323605; submitted by Applicants). In preparing the colloidal selenium composition, bovine serum albumin (BSA) was added to a selenium suspension containing anti-E.coli antibody (EP 0323605 p. 12). Lou et al. do not teach a living target cell.

Zhang et al. disclose a solution containing Se(0) and BSA (p. 28). Zhang et al. further disclose human hepatoma HepG2 cells are incubated with medium containing Se. It was noted Se induced cell growth inhibition (p. 32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a composition comprising elemental Se(0) particles and a target cell-specific carrier molecule, such as albumin, as disclosed by Lou et al. and use it as an incubation medium for the HepG2 cells of Zhang et al. (claims 7, 10-

12). The motivation to do so is given by Zhang et al., which teaches that a solution of Se(0) and albumin can successfully induce cell growth inhibition and have potential applicability in cancer treatment.

Claims 52-56 and 58-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (2001 BioFactors 15: 27-38; IDS). Zhang et al. disclose Se, in several forms, suppresses the growth of tumor cells *in vivo* and *in vitro* (p. 27). Consumption of 200 ug Se per day in cancer patients reduced mortality and depressed the incidence of many cancers including lung, colorectal and prostate cancers (p. 27). Zhang et al. further disclose Se is a putative chemopreventative agent, and though the exact mechanism for its anticarcinogenic activity still remains to be elucidated, it is likely that multiple pathways are involved (p. 27). Zhang et al. also disclose a composition comprising nano elemental selenium that is prepared with bovine serum albumin (BSA) (p. 28). To study cell viability, human hepatoma HepG2 cells were treated with Se (p. 28, methods).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a cancer cell or a human or nonhuman subject having a cancer cell by administering a composition that comprises Se(0) particles in an amount sufficient to kill the cancer cell with albumin because Zhang et al. teach the treatment of a cancer cell with a composition containing Se(0) particles and albumin and further suggest Se is a chemopreventive agent that can suppress the growth of tumor cells *in vivo* and *in vitro* (claims 52-56, 58-61, 63-66). Although Zhang et al. do not disclose a

method of reducing the level of intracellular glutathione in a cell, this element is unpatentable over Zhang et al. because Zhang et al. already disclose the treatment of a cell with a composition that comprises Se(0) particles (claim 62). Therefore, the functional limitation of reducing the level of intracellular glutathione in a cell will occur following the treatment of a cell with Se(0) particles as disclosed by Zhang et al.

Claims 26-30 and 57 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 17, 2006

ROBERT A. WAX
PRIMARY EXAMINER